DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration 93704d

October 17, 2002

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-26-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Young H. Kim, President
Hanmi, Inc.
5447 N. Wolcott Avenue
Chicago, IL 60640

Dear Mr. Kim:

On July 11, 12, 15, and 18, 2002, the Food and Drug Administration (FDA) conducted an inspection of your firm, including your food storage and repacking facility located at 5447 N. Wolcott Avenue, and your dry goods storage facility at 5435 N. Wolcott Avenue, Chicago, IL. The inspection found that you have serious deviations from the seafood hazard analysis and critical control point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123), and the regulations for Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food (cGMP) (21 CFR Part 110).

These deviations, which include an import seafood HACCP deviation previously brought to your attention in our letter of June 10, 1998, cause the mackerel and anchovies imported by your firm (covered under the seafood HACCP regulations), and cause all food products stored/repacked at your facility (covered under the food cGMP regulations) to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood that is imported in violation of the seafood HACCP regulations, and food that is stored/repacked in violation of the food cGMP regulations, are adulterated according to the Act, because they have been prepared, packed or held under insanitary conditions, whereby they may have been contaminated with filth, or may have been rendered injurious to health. You can find this Act, the seafood HACCP regulations, and the food cGMP regulations through links on FDA's home page at ***www.fda.gov***.

Our determinations and your deviations are as follows:

In regard to your import seafood operation:

- As part of your importer verification procedures, you must have written product specifications, which are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2) and (a)(2)(i). Your firm lacks written product specifications for the frozen mackerel and dried anchovies you import from [redacted] and for the canned mackerel you import from [redacted]

In regard to your food storage and food repacking operation, at the facility at 5447 N. Wolcott:

- Effective measures are not being taken to protect against contamination of food on the premises by pests, as required by 21 CFR 110.35(c).

  > Rodent fecal pellets were observed on the floor, along the office wall at the west side of the warehouse (three feet from hand garlic presses and cases of bags used for repacked grains), and in a hole in the west wall adjacent to the southwest corner of the repacking room.

  > Rodent fecal pellets and nesting material were observed on the floor in the southeast corner of the repacking room, within six feet of 50 lb.-bags of rice flour and sesame seeds, and of open containers of barley, rice powder, soybeans and mung beans.

In the facility at 5447 N. Wolcott, our investigators also reported a broken window in the south wall of the building, and a gap along the north side of the dock door. In the facility at 5435 N. Wolcott, our investigators reported a broken window in the north wall of the building. These deficiencies are in violation of 21 CFR 110.35(a).

The above-identified seafood HACCP and food cGMP deviations are not intended to be all-inclusive regarding deficiencies at your facilities. At the conclusion of the inspection, you were issued a Form FDA 483 (copy enclosed), which is a list of our investigators' observations of deviations noted during the inspection. It is your responsibility to ensure that all food products distributed by your firm, including all imported seafood products, and all foods stored/repacked at your facilities, are in compliance with the Act and all requirements of the federal regulations.

Our investigators reported that you cleaned up the areas where rodent fecal pellets were observed in the repacking room and adjacent warehouse area during our inspection. While we acknowledge these corrective actions, your response to insanitary conditions in the current inspection should include a comprehensive approach to monitor and prevent insanitary conditions and practices, in regard to both your import seafood HACCP and food cGMP programs.

We request that you take prompt action to correct any remaining violations, and implement a specific plan for ensuring that your operations are controlled.

Please provide this office, within 15 working days of receipt of this letter, a detailed response in writing, stating the actions you plan to take to correct any remaining violations, and to prevent the recurrence of all objectionable conditions. Please also provide the time within which any remaining corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action may include seizure and/or injunction.

Your reply relating to these concerns should be directed to James T. Karpus, Compliance Officer, Chicago District Office at the above address.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director

cc with enclosure: Mr. John J. Kim
Controller/Corporate Secretary
Hanmi, Inc.
5447 N. Wolcott Avenue
Chicago, IL 60640